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EXAMINER	
RAWLINGS, STEPHEN L	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 01/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/650,112	MARKOWITZ, SANFORD D.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-27 are pending in the application and are currently subject to restriction.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-7, insofar as the claims are drawn to a method for inhibiting the growth or proliferation of colon neoplasia in a subject comprising administering to the subject an agent that decreases the amount of a "ColoUp1" polypeptide present in or produced by the neoplasia, classified, for example, in class 514, subclass 44.

Group II. Claims 1-7, insofar as the claims are drawn to a method for inhibiting the growth or proliferation of colon neoplasia in a subject comprising administering to the subject an agent that decreases the amount of a "ColoUp2" polypeptide present in or produced by the neoplasia, classified, for example, in class 514, subclass 44.

Group III. Claims 1-7, insofar as the claims are drawn to a method for inhibiting the growth or proliferation of colon neoplasia in a subject comprising administering to the subject an agent that decreases the amount of a "ColoUp3" polypeptide present in or produced by the neoplasia, classified, for example, in class 514, subclass 44.

Group IV. Claims 1-7, insofar as the claims are drawn to a method for inhibiting the growth or proliferation of colon neoplasia in a subject comprising administering to the subject an agent that decreases the amount of a "ColoUp4" polypeptide present in or produced by the neoplasia, classified, for example, in class 514, subclass 44.

Group V. Claims 1-7, insofar as the claims are drawn to a method for inhibiting the growth or proliferation of colon neoplasia in a subject comprising administering to the subject an agent that decreases the amount of a "ColoUp5" polypeptide present in or produced by the neoplasia, classified, for example, in class 514, subclass 44.

Group VI. Claims 1-7, insofar as the claims are drawn to a method for inhibiting the growth or proliferation of colon neoplasia in a subject comprising administering to the subject an agent that decreases the amount of a "ColoUp6" polypeptide present in or produced by the neoplasia, classified, for example, in class 514, subclass 44.

Group VII. Claims 1-7, insofar as the claims are drawn to a method for inhibiting the growth or proliferation of colon neoplasia in a subject comprising administering to the subject an agent that decreases the amount of a "ColoUp7" polypeptide present in or produced by the neoplasia, classified, for example, in class 514, subclass 44.

Group VIII. Claims 1-7, insofar as the claims are drawn to a method for inhibiting the growth or proliferation of colon neoplasia in a subject comprising administering to the subject an agent that decreases the amount of a "ColoUp8" polypeptide present in or produced by the neoplasia, classified, for example, in class 514, subclass 44.

Group IX. Claims 8-15, insofar as the claims are drawn to a method for inhibiting the growth or proliferation of colon neoplasia in a subject comprising administering to the subject an agent that binds to and antagonzes a "ColoUp1" polypeptide, classified, for example, in class 424, subclass 138.1.

Group X. Claims 8-15, insofar as the claims are drawn to a method for inhibiting the growth or proliferation of colon neoplasia in a subject comprising administering to the subject an agent that binds to and antagonzes a "ColoUp2" polypeptide, classified, for example, in class 424, subclass 138.1.

Group XI. Claims 8-15, insofar as the claims are drawn to a method for inhibiting the growth or proliferation of colon neoplasia in a subject comprising administering to the subject an agent that binds to and antagonzes a "ColoUp3" polypeptide, classified, for example, in class 424, subclass 138.1.

Group XII. Claims 8-15, insofar as the claims are drawn to a method for inhibiting the growth or proliferation of colon neoplasia in a subject comprising administering to the subject an agent that binds to and antagonzes a "ColoUp4" polypeptide, classified, for example, in class 424, subclass 138.1.

Group XIII. Claims 8-15, insofar as the claims are drawn to a method for inhibiting the growth or proliferation of colon neoplasia in a subject comprising administering to the subject an agent that binds to and antagonzes a "ColoUp5" polypeptide, classified, for example, in class 424, subclass 138.1.

Group XIV. Claims 8-15, insofar as the claims are drawn to a method for inhibiting the growth or proliferation of colon neoplasia in a subject comprising administering to the subject an agent that binds to and antagonzes a "ColoUp6" polypeptide, classified, for example, in class 424, subclass 138.1.

Group XV. Claims 8-15, insofar as the claims are drawn to a method for inhibiting the growth or proliferation of colon neoplasia in a subject comprising administering to the subject an agent that binds to and antagonzes a "ColoUp7" polypeptide, classified, for example, in class 424, subclass 138.1.

Group XVI. Claims 8-15, insofar as the claims are drawn to a method for inhibiting the growth or proliferation of colon neoplasia in a subject comprising administering to the subject an agent that binds to and antagonzes a "ColoUp8" polypeptide, classified, for example, in class 424, subclass 138.1.

Group XVII. Claims 16-21, insofar as the claims are drawn to a therapeutic agent comprising a targeting moiety that binds to a "ColoUp1" polypeptide, classified, for example, in class 530, subclass 391.7.

Group XVIII. Claims 16-21, insofar as the claims are drawn to a therapeutic agent comprising a targeting moiety that binds to a "ColoUp2" polypeptide, classified, for example, in class 530, subclass 391.7.

Group XIX. Claims 16-21, insofar as the claims are drawn to a therapeutic agent comprising a targeting moiety that binds to a "ColoUp3" polypeptide, classified, for example, in class 530, subclass 391.7.

Group XX. Claims 16-21, insofar as the claims are drawn to a therapeutic agent comprising a targeting moiety that binds to a "ColoUp4" polypeptide, classified, for example, in class 530, subclass 391.7.

Group XXI. Claims 16-21, insofar as the claims are drawn to a therapeutic agent comprising a targeting moiety that binds to a "ColoUp5" polypeptide, classified, for example, in class 530, subclass 391.7.

Group XXII. Claims 16-21, insofar as the claims are drawn to a therapeutic agent comprising a targeting moiety that binds to a "ColoUp6" polypeptide, classified, for example, in class 530, subclass 391.7.

Group XXIII. Claims 16-21, insofar as the claims are drawn to a therapeutic agent comprising a targeting moiety that binds to a "ColoUp7" polypeptide, classified, for example, in class 530, subclass 391.7.

Group XXIV. Claims 16-21, insofar as the claims are drawn to a therapeutic agent comprising a targeting moiety that binds to a "ColoUp8" polypeptide, classified, for example, in class 530, subclass 391.7.

Group XXV. Claims 22-27, insofar as the claims are drawn to a method for identifying a candidate agent for treating colon cancer comprising identifying an agent that binds to and/or inhibits the activity of a "ColoUp1" polypeptide, classified, for example, in class 435, subclass 7.1.

Group XXVI. Claims 22-27, insofar as the claims are drawn to a method for identifying a candidate agent for treating colon cancer comprising identifying an agent that binds to and/or inhibits the activity of a "ColoUp2" polypeptide, classified, for example, in class 435, subclass 7.1.

Group XXVII. Claims 22-27, insofar as the claims are drawn to a method for identifying a candidate agent for treating colon cancer comprising identifying an agent that binds to and/or inhibits the activity of a "ColoUp3" polypeptide, classified, for example, in class 435, subclass 7.1.

Group XXVIII. Claims 22-27, insofar as the claims are drawn to a method for identifying a candidate agent for treating colon cancer comprising identifying an agent that binds to and/or inhibits the activity of a "ColoUp4" polypeptide, classified, for example, in class 435, subclass 7.1.

Group XXIX. Claims 22-27, insofar as the claims are drawn to a method for identifying a candidate agent for treating colon cancer comprising identifying an agent that

binds to and/or inhibits the activity of a "ColoUp5" polypeptide, classified, for example, in class 435, subclass 7.1.

Group XXX. Claims 22-27, insofar as the claims are drawn to a method for identifying a candidate agent for treating colon cancer comprising identifying an agent that binds to and/or inhibits the activity of a "ColoUp6" polypeptide, classified, for example, in class 435, subclass 7.1.

Group XXXI. Claims 22-27, insofar as the claims are drawn to a method for identifying a candidate agent for treating colon cancer comprising identifying an agent that binds to and/or inhibits the activity of a "ColoUp7" polypeptide, classified, for example, in class 435, subclass 7.1.

Group XXXII. Claims 22-27, insofar as the claims are drawn to a method for identifying a candidate agent for treating colon cancer comprising identifying an agent that binds to and/or inhibits the activity of a "ColoUp8" polypeptide, classified, for example, in class 435, subclass 7.1.

3. The inventions are distinct, each from the other because of the following reasons:

Any one of the inventions in Groups I-VIII, any one of the inventions in Groups IX-XVI, and any one the inventions in Groups XXV-XXXII are unrelated, or are patentably distinct, each from the others, for the following reasons:

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. See MPEP §§ 806.04 and 808.01. The inventions in Groups I-VIII, the inventions in Groups IX-XVI, and the inventions in Groups XXV-XXXII are materially different processes comprising different process steps and having a different purpose or objective or a different endpoint and criteria for success; the inventions in Groups I-VIII and the inventions in Groups IX-XVI are processes for inhibiting the growth or proliferation of a colon neoplasm, whereas the purpose or objective of the inventions of Groups XXV-XXXII is to identify an agent that binds to and/or

inhibits the activity of a polypeptide. Therefore, because the instant specification does not disclose that any of the inventions of Groups I-XVI and any of the inventions of Groups XXV-XXXII are useable together, these inventions appear unrelated.

Otherwise, any one of the inventions in Groups I-VIII, any one of the inventions in Groups IX-XVI, and any one the inventions in Groups XXV-XXXII are patentably distinct, each from the others, because the inventions are materially different processes comprising different process steps and having a different purpose or objective or a different endpoint and criteria for success. Although both the inventions in Groups I-VIII and the inventions in Groups IX-XVI are processes for inhibiting the growth or proliferation of a colon neoplasm, the former processes comprise administering to a subject a unique agent that decreases the amount of a polypeptide in or produced by a neoplasm, while the latter comprise administering to a subject a unique agent that binds to and antagonizes a polypeptide. Again, the purpose or objective of the inventions of Groups XXV-XXXII is to identify an agent that binds to and/or inhibits the activity of a polypeptide and therefore comprise performing a binding and/or activity assay.

Accordingly, the search required for examining any one of the inventions in Groups I-VIII, any one of the inventions in Groups IX-XVI, or any one the inventions in Groups XXV-XXXII is not the same, nor is it coextensive with the search required for examining any of the other inventions. Each invention consequently requires a different search; therefore, searching more than one of the inventions would constitute a serious burden. In addition, because the inventions have a different purpose or objective, or otherwise comprise different process steps and are operatively different, the inventions have acquired a different status in the art, as evidenced by their disparate classifications.

Since any of the inventions in Groups I-VIII, any one of the inventions in Groups IX-XVI, or any one the inventions in Groups XXV-XXXII are patentably distinct from the others and because the examination of more than one of these inventions could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

Inventions in Groups I-VIII are patentably distinct processes, since the inventions of each of the different groups are necessarily materially different processes that comprise administering to a subject a unique agent that decreases the amount of a different polypeptide in or produced by a neoplasm. A different gene encodes each different polypeptide; and therefore the agents (e.g.,

siRNA and antisense RNA) capable of decreasing the amount of each of the different polypeptides necessarily decrease the expression or functional activity of a different gene comprising a polynucleotide sequence that differs from that of the gene's encoding the other polypeptides. Because the polynucleotide sequences of these genes differ, and also because the amino acid sequences of the proteins encoded by these genes differ, the search necessary to examine the claims drawn to any one of the inventions of Groups I-VIII is not the same, nor is it coextensive with that required to examine claims drawn to any of the other inventions. Accordingly, each of the inventions requires a different search. Having to perform more than one search would constitute a serious burden; therefore, because the different inventions are patentably distinct, each from the others, it is proper to restrict. See MPEP § 803.

Inventions in Groups IX-XVI are patentably distinct processes, since the inventions of each of the different groups are necessarily materially different processes that comprise administering to a subject a unique agent that binds to and antagonizes a different polypeptide. Each different polypeptide comprises a different amino acid sequence and is encoded by a different gene having a unique polynucleotide sequence; and therefore the agents (e.g., antibodies) capable of binding to and antagonizing each of the different polypeptides are necessarily different. Because the agents used in the different processes differ, the search necessary to examine the claims drawn to any one of the inventions of Groups IX-XVI is not the same, nor is it coextensive with that required for examining claims drawn to any of the other inventions. Accordingly, each of the inventions requires a different search. Having to perform more than one search would constitute a serious burden; therefore, because the different inventions are patentably distinct, each from the others, it is proper to restrict. See MPEP § 803.

Inventions in Groups XVII-XXIV are patentably distinct products, since the inventions of each of the different groups are therapeutic agents comprising a targeting moiety that binds a structurally different protein having a unique amino acid sequence that differs from the amino acid sequences of the proteins to which the targeting moieties of the other therapeutic agents bind. Because the amino acid sequences of the proteins to which therapeutic agents bind differ, the search necessary to examine the claims drawn to any one of the inventions of Groups XVII-XXIV is not the same, nor is it coextensive with that required to examine claims drawn to any of the other inventions. Accordingly, each of the inventions requires a different search. Having to

perform more than one search would constitute a serious burden; therefore, because the different inventions are patentably distinct, each from the others, it is proper to restrict. See MPEP § 803.

Inventions in Groups XXV-XXXII are patentably distinct processes, since the inventions of each of the different groups are necessarily materially different processes that comprise performing a binding and/or activity assay using a different polypeptide. Each different polypeptide comprises a different amino acid sequence and is encoded by a different gene having a unique polynucleotide sequence; moreover, each polypeptide has a unique structure and function, which differs from the structures and/or functions of the other polypeptides. Because the polypeptides used in each of the different processes differ, the search necessary to examine the claims drawn to any one of the inventions of Groups XXV-XXXII is not the same, nor is it coextensive with that required to examine claims drawn to any of the other inventions. Accordingly, each of the inventions requires a different search. Having to perform more than one search would constitute a serious burden; therefore, because the different inventions are patentably distinct, each from the others, it is proper to restrict. See MPEP § 803.

The inventions of Groups XVII-XXIV and the inventions of Groups I-XVI and XXV-XXXII are unrelated because the products of Groups XVII-XXIV are not specifically used or otherwise involved in the processes of Groups I-XVI and XXV-XXXII.

4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, searching more than one invention encompassed by the claim would constitute a serious burden; therefore, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
January 6, 2005